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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,524	10/26/2001	Anne De Groot	17999-001DIV	9176

7590 04/07/2004  
MINTZ, LEVIN, COHN, FERRIS,  
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EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/055,524

Applicant(s)

GROOT, ANNE DE

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☒ Claim(s) 1-8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>02192002</u> .  | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply</u> .     |

Serial No.: 10/055,524  
Applicant: De Groot, A.

Docket No.: 17999-001DIV  
Filing Date: 10/26/01

### Detailed Office Action

#### *Status of the Claims*

Applicants' election with traverse of Group I (claims 1-8 and peptide 211) in the communication filed 11 December, 2003, is acknowledged. The traversal is based upon the premise that examining all the peptides simultaneously would not constitute an undue burden on the examiner. The examiner does not concur with this assessment. The basis for the restriction requirement was clearly set forth in the last Office action. The claimed invention is directed toward an inordinate number of sundry HIV-1 peptides (e.g., SEQ ID NOS.: 1-31, 33-85, 87-109, and 111-672). Each of the identified peptides has a different structure and attendant immunological and chemical properties. Moreover, a search of the prior art for one peptide would not be expected to yield prior art that is applicable to a structurally different peptide. Accordingly, **the requirement is still deemed to be proper and is therefore made FINAL.** Claims 9-12 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. Claims 1-8 and the peptide having SEQ ID NO.: 211 are currently under examination.

#### **37 C.F.R. § 1.821-1.825**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

**37 C.F.R. § 1.98**

The information disclosure statement filed 19 February, 2002, has been placed in the application file and the information referred to therein has been considered.

***Claim Objections***

Claims 1-8 are objected to because of the following informalities: applicants are reminded of the restriction requirement set forth in the last Office action and the election set forth in the communication dated 11 December, 2003. Accordingly, the claims should be amended to reflect the restriction requirement and election (i.e., An immunogenic composition comprising a human immunodeficiency virus type 1 (HIV-1) peptide consisting of SEQ ID NO.: 211, ...).

**37 C.F.R. § 1.75(c)**

Claim 3 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s). The claim fails to provide any further limitations that distinguish it from claim 1. Refer to M.P.E.P. § 608.01(n).

**35 U.S.C. § 112, First Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed toward a vaccine comprising a particular HIV-1 peptide (e.g., SEQ ID NO.: 211). The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

- 1) The state-of-the-art vis- -vis HIV-1 vaccine development is one of unpredictability. To date, an effective HIV-1 vaccine does not exist. This is due to several factors such as a failure to understand the correlates of human protection, a failure to understand which immunogens will produce a therapeutic or protective response, a lack of understanding of the most appropriate routes of administration and vaccination regimens, the lack of a suitable animal model in which to assess HIV-1 vaccine efficacy, the quasispecies nature of HIV-1 which leads to immune evasion, and the ability of the virus to reside in quiescent cells (Burton and Moore, 1998; Moore and Burton, 1999; Feinberg and Moore, 2002; Desrosiers, 2004).

- 2) The disclosure fails to provide any working embodiments. This is not surprising considering the problems associated with HIV vaccine development.

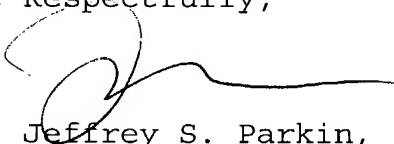
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Applicant: De Groot, A.

Accordingly, when the aforementioned factors are considered in toto, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention. Applicants may wish to amend the claim language to recite an immunogenic composition comprising the peptide of interest.

#### **Correspondence**

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively.

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

02 April, 2004